

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

**ACADEMY OF ALLERGY & ASTHMA
IN PRIMARY CARE and UNITED
BIOLOGICS, LLC D/B/A UNITED
ALLERGY SERVICES.**

Plaintiffs,

V.

**SUPERIOR HEALTHPLAN, INC. and
CENTENE CORP.**

Defendants.

[illegible]

**CIVIL ACTION NO.
5:17-CV-01122-FB (HJB)**

PLAINTIFFS' SUPPLEMENT TO DESIGNATION OF EXPERT TESTIMONY

Plaintiffs Academy of Allergy & Asthma in Primary Care (“AAAPC”) and United Biologics, LLC d/b/a United Allergy Services (“UAS”) (collectively “Plaintiffs”) hereby file this supplement to their prior designation of testifying experts as it pertains UAS’s Chief Medical Officer, Dr. Frederick Schaffer, who UAS designated under Fed. R. Civ. P. 26(a)(2)(C). After discussions with counsel for Superior, Plaintiffs seek to supplement the disclosure of the subject matter on which the witness is expected to present evidence under Federal Rule of Evidence 702, 703, or 705; and a summary of the facts and opinions to which the witness is expected to testify. Pursuant to Fed. R. Civ. P. 26(e), Plaintiffs reserve their right to further supplement disclosures for all experts including this expert as additional information is made available.

As previously disclosed to Defendants, as UAS's Chief Medical Officer Dr. Schaffer is a fact witness regarding numerous issues Superior attempts to raise in defense of its anticompetitive activity. For example, in overseeing the UAS protocol, Dr. Schaffer has personal knowledge of the safety and efficacy of the protocol and the training and scope of primary care

providers in following the protocol, including their supervision of trained UAS technicians in jointly performing the services, and the technicians' ability to perform the incident-to services in conjunction with primary care providers. As a long-time practicing board-certified allergist and researcher in the field, Dr. Schaffer is aware of UAS's protocols and services and that they are at least if not more safe and efficacious than the services delivered in an allergist's office for a properly selected patient population. Dr. Schaffer is also a person with factual knowledge because he attended HHSC meetings and at least one meeting with Superior regarding their then proposed credentialing policy and representations concerning the ability of primary care physicians to be accepted under the policy. Dr. Schaffer can testify to available continuing medical education regarding primary care physicians practicing allergy testing and immunotherapy including a program offered by the South Carolina Medical Society that Superior originally represented would be sufficient for their credentialing policy, but subsequently repudiated.

Dr. Schaffer is also qualified and may offer expert testimony concerning his research as it pertains to the UAS protocol and the protocol of allergists and specifically to rebut the conclusory assertions of Dr. Bernstein, who Superior designated. Dr. Schaffer has published extensively in peer-reviewed journals as it pertains to the UAS protocol and those publications have been produced to Defendants. Dr. Schaffer can testify to the publication process including the peer review process as it pertains to those publications. Dr. Schaffer is also aware of the publication of the Practice Parameters and can testify why those parameters are not intended to and cannot set the standard of care. Dr. Schaffer can also testify to the materials UAS uses to train physicians and technicians in comparison to the training of board-certified allergists and their technicians. Dr. Schaffer can also testify to the safety concerns of the protocols of board-

certified allergists for otherwise low-risk patient populations caused by the lack of convenience, including over reliance on in-office administration, the resulting lack of compliance, and the dangers of RUSH immunotherapy.

Dr. Schaffer can also testify concerning why Superior's requirements as it pertains to accreditation equivalent to that of a board-certified allergist is an improper and unnecessary requirement as it pertains to primary care providers. As a board-certified allergist, Dr. Schaffer participated in the accreditation programs cited by Superior and can explain why those programs extend to topics irrelevant and unnecessary for the treatment of a designated patient population. Dr. Schaffer has also extensively studied the benefits of allergen immunotherapy and can testify to its underutilization in the allergic and asthmatic population, including Medicaid enrollees.

Dr. Schaffer's curriculum vitae has been previously provided to Defendants. Moreover, Dr. Schaffer gave deposition testimony in a prior case involving Thermo Fisher Scientific, Inc. as a fact witness, and such deposition testimony has been previously produced to Defendants. Additionally, all of the materials on which Dr. Schaffer would rely have been produced by UAS or is otherwise publicly available and include the following:

- UAS training of technicians and protocols;
- UAS materials supplied to primary care physicians;
- Published articles authored by Dr. Schaffer regarding the safety and efficacy of the UAS protocol;
- Published articles regarding the safety of allergen immunotherapy whether self-administered or in an allergist's office;
- Published articles regarding the benefits of allergen immunotherapy and its underutilization and the declining allergist population;

- Published articles regarding general allergy testing and immunotherapy procedures and practices including the Practice Parameters;
- F. Schaffer, M.D., *et al.*, *The safety of self-administered allergen immunotherapy during the buildup and maintenance phases*, International Forum of Allergy & Rhinology, Int Forum Allergy Rhino/. 2015 February; 5(2): 149-156. doi:10.1002/alr.21443.
- F. Schaffer, M.D., *et al.*, *The efficacy assessment of a self-administered immunotherapy protocol*, International Forum of Allergy & Rhinology, Vol. 6, No.2, Feb. 2016.
- Meta-Analysis of Symptom+Medication Score and Quality of Life.
- Filley WV. Safety of home immunotherapy. J Allergy Clin Immunol. 2006; 117:S159
- Allergy shots at home don't raise risk of death, 2006 April; Hurst DS, Gordon BR, Fornadley JA, et al.
- Cook, P.R., Bryant, J.L., Davis, W.E., et al. *Systemic Reactions to Immunotherapy: The AAOA Morbidity and Mortality Survey*, OTOLARYNGOL. HEAD NECK SURG. 1994; 110: 487-493
- Richard L. Barnes, D.O., Safety of Home-Based Immunotherapy.
- Safety of Home-Based and Office Allergy Immunotherapy: A multicenter prospective study, Otolaryngol. Head Neck Surg. (1999).
- Hankin, C.S., et al., The Health Economics of Allergen Immunotherapy, Immunol Allergy Clinic N Am 31, 325, 339 (2011).

- Hankin C.S., *et al.*, Allergen immunotherapy and health care cost benefits for children with allergic rhinitis: a large scale, retrospective, matched cohort study. *Ann Allergy Asthma Immunol* 104, 79-85 (2010.)
- Hankin C.S., *et al.*, Allergy immunotherapy among Medicaid enrolled children with allergic rhinitis: patterns of care, resource use, and costs., *J Allergy Clin Immunol* 121, 227-232 (2008).
- AAOA, *Home Subcutaneous Immunotherapy*, American Academy of Otolaryngic Allergy's (AAOA) Clinical Care Statements (Jan. 2015).
- David B.K. Golden, M.D., et al., Stinging insect hypersensitivity: A practice parameter update 2011, *J ALLERGY CLIN IMMUNOL*, Vol. 127, No. 4 (Jan. 2011).
- <http://www.aaaai.org/ask-the-expert/rush-immunotherapy>
- Winslow, AW, Comparison of Systemic Reactions in Rush, Cluster, and Standard-Build Aeroallergen Immunotherapy, *Ann Allergy Asthma Immunol.* (Nov. 2016).
- UAS Protocols used in primary care practices
- Medical records of patients submitted with claims
- CPT Codes 95004 and 95165
- Texas Medicaid Provider Procedures Manual
- Medicare Benefits Policy Manual
- Medicare Procedures Manual
- Medicare Providers Manual
- 54 FR 4023, January 27, 1989.

- Superior's Provider's Manual
- Centene's Allergy Testing and Immunotherapy Policy.
- Superior's Allergy Credentialing Policy
- Superior's Provider Attestation Statement and Credential Checklist;
- Texas Medical Board Determination on allergy care
- Deposition testimony and exhibits to depositions of David Harmon, William Brendle Glomb, David Palafox, Holly Munin, Gilbert Handel, Karen Westbay, Susan Mills, Ahammed Hashim, David Ramos, Paula Sanders, Fred Buckwold, and Barry Lachman.

Dr. Schaffer has also reviewed the expert report of Dr. Berstein and Dr. Kongstevdt and all of the associated references and is prepared to rebut the testimony of those experts consistent with the information described above.

DATED: October 15, 2020.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of Plaintiffs' designation of testifying experts been served on all counsel of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2) on October 15, 2020.

/s/ Casey Low

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